

CRITERIA FOR PRIOR AUTHORIZATION

Zepatier® (elbasvir/grazoprevir)

PROVIDER GROUP Pharmacy**MANUAL GUIDELINES** The following drug requires prior authorization:
Elbasvir/Grazoprevir (Zepatier®)**CRITERIA FOR INITIAL APPROVAL** (must meet all of the following):**Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of elbasvir/grazoprevir therapy total for most patients or 16 weeks for genotype 1a with baseline polymorphisms or genotype 4 IFN/RBV-experienced)**

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1 or 4 hepatitis C
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not have been on previous or concurrent direct acting hepatitis C agent
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
 - Advanced fibrosis (Metavir F3 or greater)
 - Compensated cirrhosis
 - Organ transplant
 - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
 - Proteinuria
 - Nephrotic syndrome
 - Membranoproliferative glomerulonephritis
- Patient must not have moderate or severe hepatic impairment (Child-Pugh class B or C)
- Female patients on concurrent ribavirin must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during elbasvir/grazoprevir treatment
- Patient must not be concurrently prescribed a strong CYP3A inducer, efavirenz, or OATP1B1/3 inhibitor
- Patient must be tested for the presence of virus with NS5A resistance-associated polymorphisms prior to initiation of therapy
- For Genotypes 1 and/or 4: the PDL preferred drug, which covers Genotypes 1 and 4, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

CRITERIA FOR RENEWAL (must meet all of the following):

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents

LENGTH OF APPROVAL: 4 weeks for a **total of 12 weeks of treatment**4 weeks for a **total of 16 weeks of treatment** for patients with one of the following:

- Genotype 1a with baseline NS5A polymorphisms
- Genotype 4 and Peg-Interferon/ribavirin experienced

PA Criteria

Notes:

- OATP1B1 inhibitors include (but not limited to): cyclosporine, eltrombopag, lapatinib, lopinavir, rifampin, ritonavir
- OATP1B3 inhibitors include (but not limited to): cyclosporine, lopinavir, rifampin, ritonavir
- Strong CYP3A inducers include (but not limited to): phenytoin, carbamazepine, rifampin, St. John's wort

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE